REMARKS and ARGUMENTS

The Claims have been amended by amending Claims 1 and 53; canceling Claims 54 and 56; and adding new Claims 57-60.

Claims 1, 4, 7-18, 20, 21, and 51-53, 55, and 57-60 are pending in this application.

Claim 1 has been amended in limitation (f). Basis for this amendment is found, for example, in paragraph 0024 (as amended) and paragraph 0036 of the specification; and in Claim 3 as originally filed. Note M.P.E.P. § 2173.05(i), third paragraph:

> Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining.")

Because the specification positively recites SEQ ID NO: 4, SEQ ID NO: 18, and SEQ ID NO: 19 there is basis to explicitly exclude those sequences from the scope of Claim 1.

A similar amendment has been made to Claim 53, adding new limitation (d), which excludes SEQ ID NO: 4.

Claim 54 has been canceled, and replaced with new Claim 57. New Claim 57 is intended to be identical in scope to canceled Claim 54.

Claim 56 has been canceled as being redundant. As the August 20, 2007 Office Action had observed at page 2, the scope of dependent Claim 56 was identical to that of independent Claim 1.

Basis for new Claim 57 is found, for example, in paragraph 0036 of the specification, and in Claim 3 as originally filed.

Basis for new Claims 58-60 is found, for example, in paragraph 0037 of the specification, and in Claims 5 and 6 as originally filed.

The specification has been amended at Paragraph 0024 to expressly recite the sequences of two peptides that had previously been implicitly recited, through an incorporation by reference. Support for this amendment is found in Paragraphs 0101 and 0024 of the specification as originally filed; on page 126 of the incorporated Fu Dissertation (the peptide that the Dissertation had called "AMY-3"); and on the fourth page of the incorporated Aucoin Presentation, titled "Aggregation Inhibitors Used in Studies" (the peptide that the Presentation had called "AMY-2"). Accordingly, this amendment does not contain new matter. See 37 C.F.R. § 1.57, and MPEP § 608.01(p), concerning permissible incorporations by reference.

Sequence Listings; and Statement under 37 C.F.R. §§ 1.821 (f) & (g)

The sequence listings have been amended to add new SEQ ID NOs: 18 and 19, to conform the sequence listings to the contemporaneous amendments to Claim 1 and Paragraph 0024 of the specification. A paper copy of the sequence listings appears in Appendix C, and a computer-readable copy is being uploaded via EFS.

Additionally, a discrepancy was recently noted between SEQ ID NO:7 as previously shown in the Sequence Listings, and SEQ ID NO:7 as shown in paragraph 0037 of the specification. The discrepancy, in amino acid residue 6, arose through a clerical error, for which the undersigned apologizes. The discrepancy has been corrected so that SEQ ID NO: 7 in the Sequence Listings conforms to the sequence given in paragraph [0037] of the specification.

No other changes have been made in the Sequence Listings, besides those mentioned above for SEQ ID NOS: 7, 18, and 19, and updating the bibliographic information in fields <160> and <170>.

Statement under 37 C.F.R. §§ 1.821 (f) & (g). I, John H. Runnels, state over my signature and registration number appearing below that, to the best of my knowledge, information, and belief, the sequences contained in the contemporaneously uploaded computer readable sequence listings are the same as those contained in the paper copy attached below as Appendix C. For the reasons given above, it is my opinion that the revised sequence listings do not constitute new matter.

Remarks Concerning the August 7, 2007 RCE

The August 7, 2007 Request for Continued Examination had said on page 2 that the August 7, 2007 amendment restored Claim 1 to the same scope that Claim 1 had when originally filed, except for the addition of new part (f). That statement was incorrect. As the August 20, 2007 Office Action correctly observed at pages 2 and 9, amended Claim 1 also differed from Claim 1 as originally filed in other respects. The undersigned accepts responsibility for the August 7, 2007 misstatement, which resulted from an oversight on his part. The undersigned apologizes to the Office for any inconvenience resulting from the mistake.

Preliminary Remarks Concerning the Different Peptides That Have Been Called "AMY-3" in Different Sources

During the August 29, 2007 telephonic interview, the Examiner observed that the name "AMY-3" had been used to refer to different peptide sequences in two of the cited references, and that neither of those references used the name to refer to the same sequence as the one that is called "AMY-3" in the present specification. Until the Examiner pointed this out, the undersigned had not realized that such discrepancies existed.

The undersigned subsequently made a preliminary, manual survey of the specification and of the three cited references to try to clarify which peptides had been given either the name "AMY-1" or the name "AMY-3" in any of those sources.

The name "AMY-1" appears to have been used consistently throughout, namely, to refer to the peptide having SEQ ID NO: 4. However, the name "AMY-3" has been used to refer to three different peptides in three different sources. The table below summarizes the results of the undersigned's preliminary survey.[1]

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[1]This table is limited in scope, and is submitted as a courtesy only. While no errors or omissions in the table are currently known to the undersigned, no representation is made that the table is complete, nor that the table is free from error. The table addresses only amino acid sequences that are expressly listed for peptides that are specifically called "AMY-1" or "AMY-3," either in the specification or in one of the three cited references. The table does not include peptides that were given other names, nor any that lacked names. The table does not list all citations to the peptides labeled "AMY-1" and "AMY-3," but only those that expressly show amino acid sequences. The only references surveyed in preparing this table were the present specification and the three references cited in the table.

	AMY-1	AMY-3
Specification	Fig. 3 (& Par. 0030) – identical to SEQ ID NO: 4 Fig. 4 (& Par. 0031) – identical to SEQ ID NO: 4, except for $(Lys)_n$ rather than $(Lys)_6$ on C-terminus Par. 0036 – identical to SEQ ID NO: 4	Par. 0036 – identical to SEQ ID NO: 7
Organic Letters paper	page 239 – identical to SEQ ID NO: 4	
Fu Dissertation	pages 103, 104 – identical to SEQ ID NO: 4	page 126 – Dpg-Phe-Dbzg-Val-Dibg-$(Lys)_7$-NH_2 – identical to SEQ ID NO: 18
Aucoin Presentation	Fourth page, titled "Aggregation Inhibitors Used in Studies" – identical to SEQ ID NO: 4	Fourth page, titled "Aggregation Inhibitors Used in Studies" – identical to SEQ ID NO: 6

(Similarly, during the September 4, 2007 telephonic interview, the Examiner noted that the name "AMY-2" had been used to refer to different peptides in the Aucoin Presentation and the present specification. The survey described above was not repeated for peptides called "AMY-2.")

The Objection to Claim 56

The Office objected to Claim 56 as having a scope that was identical to the scope of Claim 1. Claim 56 has been canceled, making this ground of objection moot.

The § 112, Second Paragraph Rejection

Claims 1, 4, 7-18, 20, 21, 51, 52, 55, and 56 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite, with respect to part (f) of independent Claim 1. The Applicants do not necessarily agree with the interpretation that the August 20, 2007 Office Action gave to part (f) of Claim 1 (as amended August 7, 2007).

However, it is respectfully submitted that the present amendment to part (f) of Claim 1 overcomes the § 112, second paragraph rejection, in a self-evident manner that does not require extended discussion. The limitation now reads: " **(f)** said compound is neither Lys-Dibg-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2 (SEQ ID NO: 4); nor Dpg-Phe-Dbzg-Val-Dibg-$(Lys)_7$-NH_2 (SEQ ID NO: 18); nor $(Lys)_6$-Dibg-Val-Dbzg-Phe-Dpg-Lys-NH_2 (SEQ ID NO: 19)."

It is respectfully submitted that the new limitation (f) is definite, and that this ground of rejection has been overcome.

The § 119(e) Priority Date

The Office has acknowledged that Claims 53 and 54 (the latter of which has been replaced by Claim 57) are entitled to the benefit of the provisional priority date, but has taken the position that the other pending Claims are not.

Applicants do not concede that the remaining Claims are not also entitled to the benefit of the provisional filing date. Applicants reserve the right to demonstrate such priority at a later date, should the need arise. However, it is respectfully submitted that it is not necessary to decide this question for the time being. With the exception of Claims 53 and 57, in the discussion below it will be assumed for the sake of argument that the Claims might only be entitled to the benefit of the later nonprovisional filing date. Even if one makes this assumption, for the reasons given below it is respectfully submitted that all grounds of rejection should be withdrawn.

Preliminary Note Concerning the Novelty of the Independent Claims

Claims 1, 53, 57, and 58 are the independent Claims. If the independent Claims are novel and nonobvious, it then logically follows that their respective dependent Claims are necessarily novel and nonobvious as well. See M.P.E.P. § 2143.03, first paragraph. Therefore, the following discussion of novelty focuses on the rejections that have been entered against independent Claims 1 and 53.

The §§ 102 (a) and (b) Rejections of Independent Claim 1

Applicants do not waive any of their earlier arguments concerning novelty, and reserve the right to present those arguments anew at a later date if necessary.

The § 102(b) Rejection of Claim 1 over the *Organic Letters* Paper.

The Office has repeated the rejection of independent Claim 1 as being anticipated by the *Organic Letters* paper under § 102(b).

It is respectfully submitted that the present amendment to Claim 1 clearly distinguishes Claim 1 from the peptide disclosed in the *Organic Letters* paper. The *Organic Letters* paper was cited by the Office for its disclosure of the AMY-1 peptide.

Part (f) of Claim 1 has been amended to state:

> **(f)** said compound is neither Lys-Dibg-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2 (SEQ ID NO: 4); nor Dpg-Phe-Dbzg-Val-Dibg-$(Lys)_7$-NH_2 (SEQ ID NO: 18); nor $(Lys)_6$-Dibg-Val-Dbzg-Phe-Dpg-Lys-NH_2 (SEQ ID NO: 19).

The AMY-1 peptide is the same as SEQ ID NO: 4. It falls outside the scope of amended Claim 1 in light of limitation **(f)**. Thus the *Organic Letters* paper does not anticipate Claim 1 as amended.

It is respectfully submitted that this ground of rejection has been overcome.

The § 102(a) Rejection of Claim 1 over the Fu Dissertation.

The Office has repeated the rejection of independent Claim 1 as being anticipated by the Fu Dissertation under § 102(a).

It is respectfully submitted that the present amendment to Claim 1 clearly distinguishes Claim 1 from the peptides cited by the Office from the Fu Dissertation. The Fu Dissertation was cited by the Office for its disclosure of the AMY-1 peptide, and also the peptide that the Fu Dissertation at p. 126 called "AMY-3" (which is different from the peptide called "AMY-3" in the present patent application, as previously discussed).

Part (f) of Claim 1 has been amended to state:

(f) said compound is neither Lys-Dibg-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2 (SEQ ID NO: 4); nor Dpg-Phe-Dbzg-Val-Dibg-$(Lys)_7$-NH_2 (SEQ ID NO: 18); nor $(Lys)_6$-Dibg-Val-Dbzg-Phe-Dpg-Lys-NH_2 (SEQ ID NO: 19).

The AMY-1 peptide is the same as SEQ ID NO: 4. The peptide that was called "AMY-3" in the Fu Dissertation is the same as SEQ ID NO: 18. Thus both of these peptides fall outside the scope of amended Claim 1 in light of limitation **(f)**. Thus the Fu Dissertation does not anticipate Claim 1 as amended.

It is respectfully submitted that this ground of rejection has been overcome.

The Aucoin Oral Presentation.

The Office has repeated the rejection of independent Claim 1 as being anticipated by the Aucoin presentation under § 102(a).

It is respectfully submitted that the present amendment to Claim 1 clearly distinguishes Claim 1 from the peptides disclosed in the Aucoin presentation. The Aucoin presentation was cited by the Office for its disclosure of the AMY-1 peptide, and the peptide that the fourth page of the Aucoin presentation called "AMY-3" (which is different from the peptide called "AMY-3" in the present patent application, as previously discussed).

Part (f) of Claim 1 has been amended to state:

(f) said compound is neither Lys-Dibg-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2 (SEQ ID NO: 4); nor Dpg-Phe-Dbzg-Val-Dibg-$(Lys)_7$-NH_2 (SEQ ID NO: 18); nor $(Lys)_6$-Dibg-Val-Dbzg-Phe-Dpg-Lys-NH_2 (SEQ ID NO: 19).

The AMY-1 peptide is the same as SEQ ID NO: 4, which falls outside the scope of amended Claim 1 in light of limitation **(f)**.

The peptide that the Aucoin presentation called "AMY-3" is the same as SEQ ID NO: 6. That peptide falls outside the scope of Claim 1 because it does not have a group corresponding to $(S)_n$ wherein *n* is from 4 to 10. See limitation **(c)** of Claim 1.

Thus neither of the cited peptides anticipates Claim 1.

To clarify some minor points that were raised by the Examiner during the August 29, 2007 telephonic interview, please see Paragraphs 3 and 4 of the contemporaneously-submitted new Declaration from Robert Hammer.

It is respectfully submitted that the this ground of rejection has been overcome or should otherwise be withdrawn.

The Rejection of Claim 53 over the *Organic Letters* Paper.

The Office has repeated the rejection of independent Claim 53 as being anticipated by the *Organic Letters* paper under § 102(a).

It is respectfully submitted that the present amendment to Claim 53 clearly distinguishes Claim 53 from the peptide disclosed in the *Organic Letters* paper. The *Organic Letters* paper was cited by the Office for its disclosure of the AMY-1 peptide.

Part (d) of Claim 53 has been amended to state:

> **(d)** said compound is not Lys-Dibg-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2 (SEQ ID NO: 4).

The AMY-1 peptide is the same as SEQ ID NO: 4. It falls outside the scope of amended Claim 53 in light of limitation **(d)**. Thus the *Organic Letters* paper does not anticipate Claim 53 as amended.

It is respectfully submitted that this ground of rejection has been overcome.

§ 102 Summary

It is respectfully submitted that all prior art rejections have been overcome.

Interview Summary

A brief telephonic interview was conducted on August 28, 2007, followed by a lengthier telephonic interview on August 29, 2007, and another brief telephonic interview on September 4, 2007. All three interviews were conducted between Examiner Russel and the undersigned. The following summary is presented in compliance with M.P.E.P. § 713.04.

(A) There were no exhibits or demonstrations.

(B) The principal Claims discussed were Claims 1, 53, and 57-60.

(C) The references discussed were the *Organic Letters* paper, the Fu Dissertation, and the Aucoin presentation.

(D) The principal amendments discussed were those shown in the present amendment; and earlier, informal draft versions of the amendments that had been faxed to the Examiner on August 27, 28, and 31, 2007 for discussion purposes.

(E) The general thrust of the discussions was whether, for the reasons given in the present remarks, the present amendments would place the application in condition for allowance.

(F) (1) There was also a brief discussion to the effect that there is no necessary inconsistency in stating that two claims in a single patent application can have different inventors, even where one of the claims is generic to the other. (2) There was also a discussion about the discrepancies in peptide nomenclature, as discussed above.

(G) (1) A tentative agreement was reached that – subject to further review and consideration by the Examiner – the amendments that are being presented here, along with the new Declaration from Dr. Hammer, should place the application in

condition for allowance. (2) The undersigned and the Examiner did not reach agreement as to whether adding SEQ ID NO: 18 and SEQ ID NO: 19 to the application would or would not constitute new matter. However, that question appears to be largely academic. If the undersigned correctly understands the Examiner's position, the disagreement concerned not whether SEQ ID NO: 18 and SEQ ID NO: 19 could properly be excluded from the scope of Claim 1, but instead centered on whether a hypothetical new Claim directed specifically to SEQ ID NO: 18 or SEQ ID NO: 19 would raise a question of new matter. However, no such Claim has been presented, so it is believed that this question should now be moot. As a practical matter, it is necessary to include the sequences in the specification (or at least in the Sequence Listing), to be able to properly cite the sequences within part (f) of Claim 1, in the manner required by 37 C.F.R. § 1.821(d).

Miscellaneous: Remarks Concerning the August 7, 2007 Declaration

Following are brief remarks concerning the August 7, 2007 Declaration of Dr. Hammer. These remarks may be moot in one sense. Namely, in light of the present amendments to Claims 1 and 53, it may no longer be necessary to consider the Declaration in determining whether the § 102 rejections should be withdrawn.

But in another sense, these remarks may not be completely moot. The August 20, 2007 Office Action had identified purported inconsistencies in the Declaration. The purpose of these remarks is to clarify the record that the statements in question are, in fact, entirely consistent.

As one example, the paragraph bridging pages 10-11 of the August 20, 2007 Office Action stated:

> The Fu dissertation is applied against Applicants' claims because of the dissertation's disclosure of the peptides AMY-3 and AMY-1. Section 8 of the Hammer declaration does not explicitly state who are the inventors of these two peptides. Paragraph 8(d) states that any disclosure by the Fu Dissertation of subject matter encompassed by the rejected claims, other than disclosure of peptide synthesis, was derived from McLaughlin and Hammer. This paragraph therefore implies that peptides AMY-3 and AMY-1 were invented by McLaughlin and Hammer. However, at least for peptide AMY-1, this implication is contradicted by

the statement in paragraphs 7(b) and 7(c) that McLaughlin, Fu, Miller, and Hammer are the inventors of the peptide AMY-1.

However, there is no inconsistency in saying that different groups of inventors conceived different inventions. To the contrary, 35 U.S.C. § 116 recognizes that different claims can have different inventors: "Inventors may apply for a patent jointly even though . . . each did not make a contribution to the subject matter of every claim of the patent."

The peptide AMY-3 will not be discussed further in this context. As previously noted, different sources had used the name "AMY-3" to refer to different sequences. Neither of the cited references disclosed the same "AMY-3" as the peptide given this name in the present application.

Paragraph 5 of the August 7, 2007 Declaration stated that McLaughlin and Hammer were the inventors of Claims 1, 7, 8, 20, 21, 51-53, and 55.

The Office stated that "Section 8 of the Hammer declaration does not explicitly state who are the inventors of these two peptides [AMY-3 and AMY-1]." However, Paragraphs 7(b) and 9(b) of the August 7, 2007 Declaration unequivocally identify the inventors of the peptide AMY-1: Hammer, McLaughlin, Fu, and Miller. See also Paragraphs 3(b) and 4(b) of the contemporaneously-submitted new Declaration by Dr. Hammer.

To state that McLaughlin and Hammer were the inventors of the generic invention of Claim 1 does not imply that McLaughlin and Hammer were also the (only) inventors of a particular, specific peptide. This is the case whether or not the specific peptide falls within the scope of generic Claim 1.

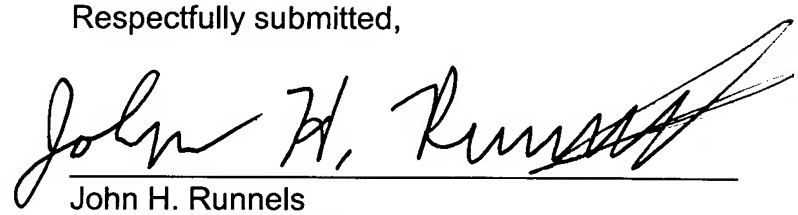
There is no inconsistency in recognizing both: ***(i)*** that Hammer and McLaughlin made the generic invention of Claim 1 (August 7, 2007 Declaration, Paragraph 5), and also ***(ii)*** that Hammer, McLaughlin, Fu, and Miller invented a specific peptide such as AMY-1 (August 7, 2007 Declaration, Paragraphs 7(b) and 9(b); see also Paragraphs 3(b) and 4(b) of the contemporaneously-submitted new Declaration by Dr. Hammer.)

Conclusion

Allowance of Claims 1, 4, 7-18, 20, 21, and 51-53, 55, and 57-60 at an early date is respectfully requested.

Strictly in the alternative, if the Office should identify any minor remaining issues, then the Examiner is respectfully requested to contact the undersigned by telephone to discuss such matters further, in order to conclude prosecution expeditiously.

Respectfully submitted,



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